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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/827,345	04/06/2001	Jean-Claude Chermann	065691-0216	4575

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EXAMINER

HILL, MYRON G

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 01/14/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/827,345

Applicant(s)

CHERMANN ET AL.

Examiner

Myron G. Hill

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26- 30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Election/Restrictions

This action is in response to letter of 10/23/02. All claims were canceled and new claims 26- 30 were added. The restriction requirement is moot in light of the amendment, and no new restriction is required.

This action is on claims 26- 30.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 26- 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear how the term "cryptic epitope" on page 3, lines 21- 37 is defined. In lines 23- 25, it is not clear how the immune response is defined in that the epitope is hidden and recognized as foreign by the immune system? From this definition it is not clear what function or properties the antibody has that recognizes the cryptic epitope. In claims 28 and 29, it is not clear what the metes and bounds of "at risk of an HIV infection." On page 19, top part, samples from patients who do not progress are disclosed but they are clearly infected because they are seropositive. Or is it meant that a never-exposed-to-HIV individual can be tested to determine if they will become HIV infected? Claim 28 is also not clear because the

method is not complete. Where is the epitope detected? Is the detection of the epitope with the antibody a positive result?

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 28 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for using a peptide to detect the presence of a particular antibody associated with beta-2-microglobulin and using a peptide to block the neutralizing effects of an antibody in an in vitro HIV infection, does not reasonably provide enablement for diagnosing a patient having HIV infection using an antibody to detect a cryptic epitope. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Example 1 is directed to making an antibody, example 2 is directed to making a mutant virus, example 3 is directed to use of a selected peptide to detect antibodies, example 4 is directed to detecting antibodies that neutralize various HIV isolates, and example 5 is directed to a method of detecting equivalent peptides.

It is known in the art that beta-2-microglobulin is found in the urine of patients with certain immune system disorders.

While working examples are not required, there has been no disclosure or showing that an antibody to this cryptic epitope (PKI), has the function that it does

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detect beta-2-microglobulin of HIV infected persons and not in uninfected persons. It is also not clear that the antibody used to detect cryptic epitope would be diagnostic or that the antibody recognizes the epitope when it is hidden, in other words, an epitope with the "cryptic" property is recognized by the antibody in a way that shows the "cryptic" nature of the epitope. The specification lists many embodiments of the invention (pages 4- 12) but does not list the use of antibody as a diagnostic to detect cryptic epitope.

Thus, due to the unpredictability of the art, the diverse range of immunological conditions, the lack of examples that show antibody used as a diagnostic to test for cryptic epitope, the fact that using peptide to detect antibody is not the same test, it is concluded that it would require undue experimentation to use the invention as claimed.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 26 and 27 are rejected under 35 U.S.C. 101 because they read on a product of nature. Human beings that contain the antibody are encompassed by the claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 26, 27, 29, and 30 are rejected under 35 U.S.C. 102(b) as anticipated by Liabeuf.

Liabeuf discloses monoclonal antibodies that bind to epitopes of beta-2-microglobulin including C21.48A1 that bound to an internal form but did not bind to beta-2-microglobulin when complexed with HLA on the cell surface as well as antibody B1G6 (see pages 1542- 1543, page 1547, column 2, third full paragraph).

Liabeuf is silent on the sequence of beta-2-microglobulin but the motif Pro-Lys-Ile (or PKI) is found in the sequence of the protein. See Sheet with Accession # gi:70065, residues 110- 112.

Liabeuf is silent on the sequence of beta-2-microglobulin to which the antibody binds; however, because it is a monoclonal antibody, it recognizes one specific site on the beta-2-microglobulin and the epitope has "cryptic" properties.

Peptides containing epitopes are known as antigens (see Harlow page 76). Epitopes recognized by antibodies are well known in the art to be less than 15 amino acids in length. It is noted the length of epitope does not limit the length of peptide containing the epitope.

The C21.48A1 antibody of Liabeuf meets the limitation of binding "to at least one isolated beta-2-microglobulin cryptic epitope."

Conclusion

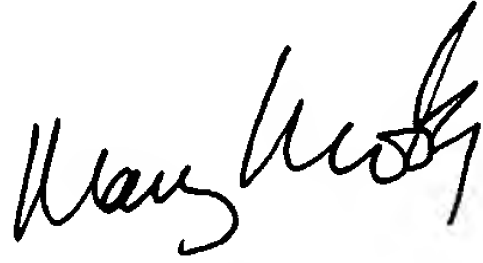
No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 703-308-4521. The examiner can normally be reached on 9am-6pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4247. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Myron G. Hill
Patent Examiner
January 12, 2003


MARY E. MOSHER
PRIMARY EXAMINER
GROUP 1800-1600